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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,933	03/08/2004	Jan Zavada	D-0021.2-2	2689

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/795,933	ZAVADA ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-35 and 39-55* is/are pending in the application.

4a) Of the above claim(s) *39-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *April 2, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's election with partial traverse of claims 31-35 and 53-55 (reciting SEQ ID NO:3) in the reply filed on March 16, 2006 is acknowledged. Applicants traversed only on the secondary restriction requirement among the three different SEQ ID NOs. The traversal is on the ground(s) that SEQ ID NOs: 3, 4, and 7 are not distinct or independent.

Applicant's arguments, see page 7-8, filed on March 16, 2006, with respect to withdrawing restriction among SEQ ID NOs: 3, 4, and 7 have been fully considered and are persuasive. The restriction among SEQ ID NOs: 3, 4, and 7 of claim 55 has been withdrawn.

Pending Claims

Claims 1-30 and 36-38 have been cancelled. Claims 39-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Accordingly, claims 31-35 and 53-55 are under examination.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the

printer is limited. Currently, the instant abstract exceeds 150 words in length. Appropriate correction is required.

The form and legal phraseology often used in patent claims, such as "said," should be avoided. The instant abstract contains the term, "said". Appropriate correction is required.

The instant specification contains duplicate headings, "Antisense MN Nucleic Acid Sequences" on pages 91 and 92. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-33 recite the limitation "said MN antisense nucleotide" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 31, which claims 32-33 depend from recite "MN antisense oligonucleotide", not "MN antisense nucleotide". Appropriate correction is required.

Double Patenting

Claims 31-35 and 53-55 are rejected on the ground of nonstatutory obviousness-type double patenting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 11 of U.S. Patent No. 5,387,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Claims 31-34 are directed to an MN antisense construct comprising a nucleic acid sequence complementary to the MN cDNA sequence, SEQ ID NO:1 (claim 33) or SEQ ID NO:5 (claims 31-32 and 34-35), which is operably linked to an expression control sequence in a vector, wherein said vector is derived from a bacteriophage.

Claims 5 and 11 of U.S. Patent No. 5,387,676 are directed to an isolated nucleic acid that hybridizes to the instant SEQ ID NO:1, wherein said nucleic acid is contained in a bacterial cloning vector and is operatively linked to an expression control sequence in said vector. Claims 5 and 11 of U.S. Patent No. 5,387,676 do not recite SEQ ID NO:5.

Since both SEQ ID NOs: 1 and 5 are MN cDNA sequences and SEQ ID NO:5 comprises the entire length of SEQ ID NO:1, it would have been obvious to one of ordinary skill in the art to at the time of instant invention make an MN cDNA construct comprising either SEQ ID NO:1 or 5 that is operably linked to an expression control sequence within a bacterial vector. The skilled artisan would have been motivated to make the instant MN cDNA antisense construct with a reasonable expectation of success because the reference claims of U.S. Patent No. 5,387,676 teach an MN cDNA antisense construct meeting all the structural limitations of the instant claims 31-34. Accordingly, the instant application claims 31-34 are not patentably distinct from the reference claims 5 and 11 because the examined application claims 31-34 would have been obvious over the reference claims 5 and 11.

Claim 35 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,387,676, in view of claim 11 of WO 92/04903.

Claim 35 recites a composition comprising a pharmaceutically acceptable carrier and the MN antisense construct.

Claim 11 of U.S. Patent No. 5,387,676 teaches all the structural limitations of the MN antisense construct that correspond to those of claim 35 as described above. The Patent No. 5,387,676 does not teach a composition comprising a pharmaceutically acceptable carrier and the MN antisense construct.

Claim 11 of WO 92/04903 recites, "A pharmaceutical composition, in dosage unit form, comprising an antisense oligonucleotide that selectively inhibits expression of a viral antigen, in an amount sufficient to effect said selective inhibition, together with a pharmaceutically acceptable carrier".

It would have been obvious to one of ordinary skill in the art at the time of invention to make the MN antisense construct further comprising a pharmaceutically acceptable carrier in light of claim 11 of U.S. Patent No. 5,387,676 and claim 11 of WO 92/04903. One of ordinary skill in the art would have been motivated to make a pharmaceutical composition, with a reasonable expectation of success, comprising an antisense construct and a pharmaceutically acceptable carrier as taught by WO 92/04903 for the MN antisense construct of U.S. Patent No. 5,387,676 in order to treat or diagnose neoplastic diseases as taught by U.S. Patent No. 5,387,676. Accordingly, the instant application claim 35 is not patentably distinct from the reference claim 11 of U.S. Patent No. 5,387,676, in view of the secondary reference claim 11 of WO 92/04903.

Claim 53 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,387,676, in view of U.S. Patent No. 5,196,333.

Claim 53 recites an MN antisense construct comprising a nucleic acid sequence complementary to the MN cDNA sequence, SEQ ID NO:5, which is operably linked to an expression control sequence in a vector, wherein said expression control sequence comprises a nucleic acid sequence derived from the MN promoter.

The instant specification discloses that the MN promoter consensus sequences are CAT (CCAAT) or TATA (ATAAATATA) on page 29.

Claim 11 of U.S. Patent No. 5,387,676 discloses all the structural limitations of the MN antisense construct of claim 53 as described above. Claim 11 of U.S. Patent No. 5,387,676 does not teach linking the MN antisense construct to an expression control sequence derived from the MN promoter such as TATA box.

U.S. Patent No. 5,196,333 teaches that the TATA box, capping sequence, and CAAT sequence from the 5' non-transcribing control sequences are expression control sequences that can be used as a promoter for transcriptional control for the operably linked gene (columns 26-27). Further, U.S. Patent No. 5,196,333 teaches that an antisense DNA strand may be operably linked to such promoter in an expression vector (column 29).

It would have been obvious to one of ordinary skill in the art at the time of invention to operably link the MN antisense construct to the MN promoter sequence containing TATA box in order to control the expression of the MN antisense construct as taught by U.S. Patent No. 5,196,333. One of ordinary skill in the art would have been motivated to make an MN antisense construct operably linked to a consensus gene expression control sequences as a promoter for

transcriptional control for the operably linked antisense as taught by U.S. Patent No. 5,196,333 with a reasonable expectation of success. Accordingly, the instant application claim 53 is not patentably distinct from the reference claim 11 in view of the teachings of U.S. Patent No. 5,196,333.

Claims 54-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,387,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Claims 54-55 recite an MN antisense construct comprising an MN antisense oligonucleotide consisting of SEQ ID NO:3 or 4, which is operably linked to an expression control sequence in a vector, wherein said MN antisense oligonucleotide is between 19 and 29 nucleotides in length.

MN antisense oligonucleotides consisting of SEQ ID NO:3 (29 nucleotides in length) and SEQ ID NO:4 (19 nucleotides in length) are disclosed in the above U.S. Patent No. 5,387,676 (see column 24 and sequence listing), and moreover, all the structural limitations of the MN antisense construct are recited in claim 11 of the above U. S. Patent. It would have been obvious to one of ordinary skill in the art at the time of invention to make an MN antisense construct comprising the MN antisense oligonucleotide SEQ ID NO:3 or 4 that had been already disclosed in the U.S. Patent No. 5,387,676. One of ordinary skill in the art would have been motivated to make an antisense construct in a vector for the instant SEQ ID NOs:3 and 4 with a reasonable expectation of success because U.S. Patent No. 5,387,676 discloses SEQ ID NOs:3 and 4 as effective MN antisense oligonucleotide sequence. Accordingly, the instant application claims 54-

55 are not patentably distinct from the reference claim 11 in view of the disclosure of U.S. Patent No. 5,387,676.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER

dhs
June 20, 2006